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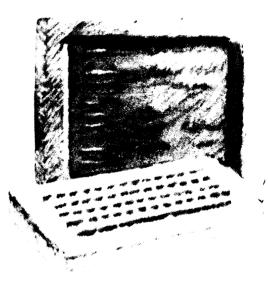
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PROGRAM PROFILE

USC CENTER FOR COLORECTAL DISEASES

he USC Center for Colorectal Diseases is a university-based

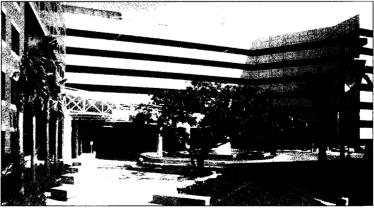
A CASE STUDY

A 37-year-old male presented with a 17 year history of ulcerative colitis. On rectal exam, a 2 cm. polyp on a stalk was noted and removed. It contained an invasive carcinoma. Surgical judgments and alternatives for the management of this problem are complex.

Current understanding on the margins of resection, use of adjuvant therapy, and the technical issues of continence preservation, interplay in this complex case. Recognition of the appropriate use of nerve sparing rectal dissection with wide lymphadenectomy allowed for an adequate cancer procedure while preserving the sphincter mechanism. A compliant and capacious pouch was created and intestinal continuity was restored.

The patient has recovered, retained his sexual potency and maintained fecal continence with five bowel movements a day. He is fully active and continues long distance running as a hobby.

private practice that offers the full range of advanced diagnostic and treatment alternatives for patients with colorectal disease and fecal incontinence. Offering advanced expertise in a university setting, the Center provides primary *and* tertiary management of colorectal disease, including inflammatory bowel disease, ulcerative colitis and Crohn's disease. It conducts sophisticated physiological tests to evaluate anorectal physiology in patients who have difficulty with fecal incontinence.



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Innovative Surgical Alternatives

The Center's specialists have expertise in the surgical alternatives to ileostomy and colostomy, including:

- Koch Pouch: This continent intestinal reservoir allows patients to store waste and control its discharge after coloproctectomy, thus eliminating the need for an external appliance.
- Ileal Pouch-Anal Anastomosis: In this procedure, surgeons create a pouch out of the terminal ilium and sew it to the anal muscles, and perform a temporary ileostomy. Six to eight weeks later, they close the ileostomy, and patients can defecate normally.
- Laparoscopically Assisted Colectomy: Surgeons can now effectively remove segments of the colon through this minimally invasive technique.

The Center's comprehensive services include:

- Colonoscopy
- Management of recurrent colorectal cancer
- Anorectal physiologic studies
- Evaluation of continence disorders
- Continence preserving and restoring surgical procedures
- Post-operative pain management, rehabilitation and education
- Research activities including the physiology of continence and surgical techniques
- Educational activities to support physicians in the development of current surgical techniques

Center surgeons perform all major surgeries at USC University Hospital or USC/Norris Cancer Center. Both facilities provide the latest in technology, patient care and dedicated colorectal trained nurses.

Physician Support and Education

As an academically based program, the Center is dedicated to providing continuing education and support for physicians practicing in the community setting. Physicians are encouraged to contact USC PACE for patient consultation or program information.

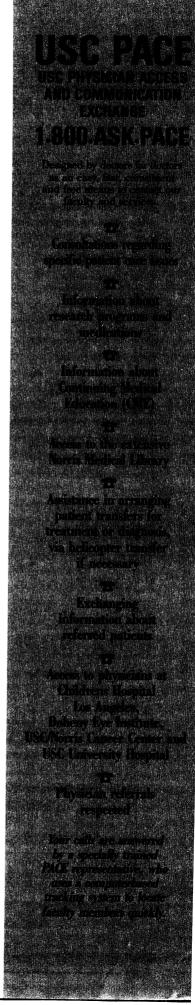
About the Director

Robert W. Beart, Jr., M.D., Professor of Surgery at the USC School of Medicine, serves as Director of the USC Center for Colorectal Diseases. He is a world-renowned specialist in colon and rectal surgery, with extensive experience in performing and refining surgical alternatives to ileostomy and colostomy and laparoscopic colon resection.

Dr. Beart received his medical degree from Harvard Medical School, and completed his internship and residencies at the University of Colorado Medical Center in Denver. He did a transplant fellowship (liver and kidney) at the University of Colorado, and a colon and rectal fellowship at the Mayo Clinic Rochester. For more than a decade, he served as Chairman, Colon and Rectal Surgery at the Mayo Clinic Rochester, and was named the Caywood Professor of Surgery. At the Mayo Clinic Scottsdale (Arizona), he was Chairman, Department of General Surgery. He joined USC University Hospital in 1992.

Dr. Beart, a member of numerous professional organizations, is the immediate Past President of the American Society of Colon and Rectal Surgeons. He is widely published in peer review journals, is the editor of Diseases of the Colon & Rectum, and is a much sought after lecturer.

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Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon* is indicated as a sympathicolytic and mydriatric. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug. 1,2 Also dizziness, headache, skin flushing reported when used orally. 1,3

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence. 1.3.4 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.3

How Supplied: Oral tablets of YOCON® 1/12 gr. 5.4mg in bottles of 100's NDC 53159-001-01, 1000's NDC 53159-001-10 and Blister-Paks of 30's NDC 53159-001-30

A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981, Goodman, Gilman — The Pharmacological basis

of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.

Weekly Urological Clinical Letter, 27:2. July 4, 1983 A. Morales et al., The Journal of Urology 128

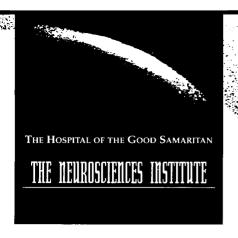




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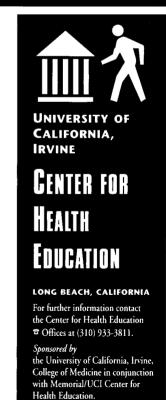
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Provides comfortable, prompt relief of allergic rhinitis and effective QD dosing

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Duration of acquisition of the PET image was approximately 55 minutes due to 11 C decay ($t^{1}/2$ of 20 minutes). 1 (n=2)

- Nasacort provides prompt relief for many patients symptom reduction may occur as soon as 24 hours after starting therapy 4
- Nasacort provides effective QD dosing 2 puffs/nostril/day effectively controls symptoms in most patients; however, QD dosing can be increased to 4 puffs/nostril/day when necessary

Please see brief summary of prescribing information on adjacent page.
* In doses up to 440 mcg/day. 3

Nasacort...Once Is Enough





For Intranasal Use Only Shake Well Before Using

BRIEF SUMMARY

CONTRAINDICATIONS: Hypersensitivity to any of the ingredients of this preparation

WARNINGS: The replacement of a systemic corticosteroid with a topical corticoid can be accompanied by signs of adrenal insufficiency and, in addition, some patients may experience symptoms of withdrawal, e.g., joint and/or muscular pain, lassitude and depression. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticostes should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long-term systemic corticosteroid treatment, too rapid a decrease in systemic conticosteroids may cause a severe

exaceruation or treir symptoms.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant doses of corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

The use of Nasacort Nasal Inhaler with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (IHPA) suppression compared to a therapeutic dose of either one alone. Therefore, Nasacort Nasal Inhaler should be used with caution in patients already receiving alternate-day prednisone treatment for any disease.

Generat: In clinical studies with triamcinolone acetonide administered intranasally, the development of localized infections of the nose and pharynx with Candida albicans has rarely occurred. When such an infection develops it may require treatment with appropriate local therapy and discontinuance of treatment with Nasacort Nasal Inhaler.

Triamcinolone acetonide administered intranasally has been shown to be absorbed into the systemic circulation in humans. Patients with active rhinitis showed absorption similar to that found in normal volunteers. Nasacort at 440 mcg/day for 42 days did not measurably affect adrenal response to a six hour cosyntropin test. In the same study prednisone 10 mg/day significantly reduced adrenal response to ACTH over the same period (see CLINICAL TRIALS

Nasacort Nasal Inhaler should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract or in patients with untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex.

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, a corticosteroid should be used with caution until healing has occurred. As with other nasally inhaled corticosteroids, nasal septa perforations have been reported in rare instances.

when used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, Nasacort Nasal Inhaler should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy Information for Patients: Patients being treated with Nasacort Nasal Inhaler should receive the following information and instructions

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to obtain medical advice. Patients should use Nasacort Nasal Inhaler at regular intervals since its effectiveness depends on its regular use. A decrease in symptoms may occur as soon as 12 hours after starting steroid therapy and generally can be expected to occur within a few days of initiating therapy in allergic rhinitis. The patient should take the medication as directed and should not exceed the prescribed

dosage. The patient should contact the physician if symptoms do not improve after three weeks, or if the condition worsens. Nasal irritation and/or burning or stinging after use of the spray occur only rarely with this product. The patient should contact the physician if they occur. For the proper use of this unit and to attain maximum improvement, the patient should read and follow the accompanying patient instructions carefully. Because the amount dispensed per puff may not be consistent, it is important to shake the canister well. Also, the canister should be discarded after 100 actuations

discarded after 100 actuations.

Carcinogenesis, Mutagenesis: Animal studies of triamcinolone acetonide to test its carcinogenic potential are underway.

Impairment of Fertility: Male and female rats which were administered oral triamcinolone acetonide at doses as high as 15 mcg/kg/day (110 mcg/m²/day, as calculated on a surface area basis) exhibited no evidence of impaired fertility. The maximum human dose, for comparison, is 6.3 mcg/kg/day (240 mcg/m²/day). However, a few female rats which received maternally toxic doses of 8 or 15 mcg/kg/day (60 mcg/m²/day or 110 mcg/m²/day, respectively, as calculated on a surface area.

surface area basis) exhibited dystocia and prolonged delivery. Developmental toxicity, which included increases in fetal resorptions and stillbirths and decreases in pup body weight and survival, also occurred at the maternally toxic doses (2.5 - 15.0 mcg/kg/day or 20 - 110 mcg/m²/day, as calculated on a surface area basis). Reproductive performance of female rats and effects on fetuses and offspring were comparable between groups that received pla and non-toxic or marginally toxic doses (0.5 and 1.0 mcg/kg/day or 3.8 mcg/m²/day and 7.0 mcg/m²/day).

7.0 mcg/m²/day).

Pregnancy: Pregnancy Category C. Like other corticoids, triamcinolone acetonide has been shown to be teratogenic in rats and rabbits. Teratogenic effects, which occurred in both species at 0.02, 0.04 and 0.08 mg/kg/day (approximately 135, 270 and 540 mcg/m²/day in the rat and 320, 640 and 1280 mcg/m²/day in the rabbit, as calculated on a surface area basis), included a low incidence of cleft palate and/or internal hydrocephaly and axial skellet defects. Teratogenic effects, including CNS and cranial malformations, have also been observed in non-human primates at 0.5 mg/kg/day (approximately 6.7 mg/m²/day). The doses of 0.02, 0.04, 0.08, and 0.5 mg/kg/day used in these toxicology studies are approximately 12.8, 25.5, 51, and 318.7 times the minimum recommended dose of 110 mcg of Nasacort per day based on a patient body weight of 70 kg. Administration of aerosol by inhalation to pregnant rats and rabbits produced embryotoxic and fetotoxic effects which were comparable to those produced by administration by other routes. There are no adequate and well-controlled studies in pregnant women. Triamcinolone acetonide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

justness the potential risk to the fetus.

Experience with oral corticoids since their introduction in pharmacologic as opposed to physiologic doses suggests that rodents are more prone to teratogenic effects from corticoids than humans. In addition, because there is a natural increase in glucocorticoid production during pregnancy, most women will require a lower exogenous steroid dose and many will not need corticoid treatment during pregnancy.

Nonteratogenic Effects: Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

Nursing Mothers: It is not known whether triamcinolone acetonide is excreted in human milk.

Receause other corticosteroids are excreted in human milk cuttions bould be exercised when.

Because other corticosteroids are excreted in human milk, caution should be exercised when Nasacort Nasal Inhaler is administered to nursing women.

Nasacort Nasal Inhaler is administered to nursing women.

Pediatric Use: Safety and effectiveness have not been established in children below the age of 12. Oral corticoids have been shown to cause growth suppression in children and teenagers, particularly with higher doses over extended periods. If a child or teenager on any corticoid appears to have growth suppression, the possibility that they are particularly sensitive to this effect of steroids should be considered.

ADVERSE REACTIONS: In controlled and uncontrolled studies, 1257 patients received treatment with intransal triamcinolone acetonide. Adverse reactions are based on the 567 patients who received a product similar to the marketed Nasacort canister. These patients were treated for an average of 48 days (range 1 to 117 days). The 145 patients enrolled in uncontrolled studies received treatment from 1 to 820 days (average 332 days).

The most prevalent adverse experience was headache, being reported by approximately 18% of the patients who received Nasacort. Nasal irritation was reported by ever than 5% of the patients who received Nasacort and included: dry mucous membranes, naso-sinus congestion, throat discomfort, sneezing, and epistaris. The complaints do not usually interfere with treatment and in the controlled and uncontrolled studies approximately 1% of patients have discontinued because of these nasal adverse effects.

In the event of accidental overdose, an increased potential for these adverse experiences may be expected, but systemic adverse experiences are unlikely (see OVERDOSAGE section).

OVERDOSAGE: Acute overdosage with this dosage form is unlikely. The acute topical application of the entire 15 mg of the canister would most likely cause nasal irritation and headache. It would be unlikely to see acute systemic adverse effects if the nasal application of the 15 mg of triamcinolone acetonide was administered all at once.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription. Please see product circular for full prescribing information.

1. Data on file, Rhône-Poulenc Rorer Pharmaceuticals Inc. 2. Ziemniak JA: Pharmacokinetics of intranasal triamcinolone acetonide. *J Respir Dis* 1991;12 (3, Suppl):S41-S42. 3. Feiss G, Morris R, Rom D, et al: A comparative study of the effects of intranasal triamcinolone acetonide aeroso (ITAA) and prednisone on adrenocortical function. J Allergy Clin Immunol 1992;89:1151-1156. Findlay S, Huber F, Garcia J, et al: Efficacy of once-a-day intranasal administration of triam cinolone acetonide in patients with seasonal allergic rhinitis. Ann Allergy 1992;68(3):228-232.



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16th Annual International Gastroenterology Conference February 8-11, 1995 • The Hilton, Walt Disney World Village

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15th Annual Critical Care Medicine Conference April 6-9, 1995 • The Hilton, Walt Disney World Village

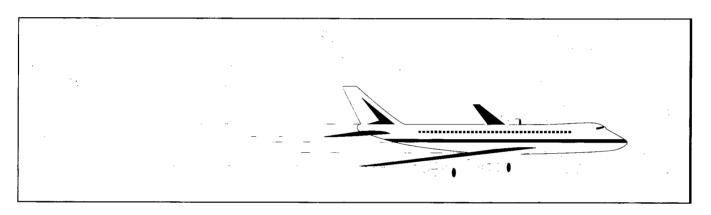
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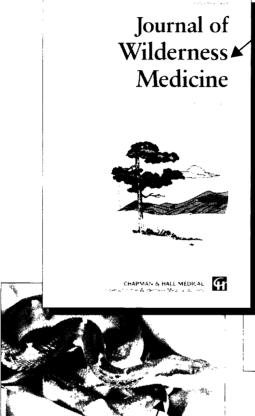
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Lachesis muta-the bushmaster. Review: Central and South American pit vipers. Davidson et al. JWM Vol. 4, Issue 4, 1993.

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CONTRAINDICATIONS: Hypersensitivity to any of the ingredients of this preparation

WARNINGS: The replacement of a systemic corticosteroid with a topical corticoid can be warnings: The replacement of a systemic corticosterion with a topical corticoto can be accompanied by signs of adrenal insufficiency and, in addition, some patients may experience symptoms of withdrawal, e.g., joint and/or muscular pain, lassitude and depression. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticoids should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long-term systemic corticosteroid treatment, too rapid a decrease in systemic corticosteroids may cause a severe exceptacing of their companies. exacerbation of their symptoms

exaceroation of their symptoms.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant doses of corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

The use of Nasacort Nasal Inhaler with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (IFIA) suppression compared to a therapeutic dose of either one alone. Therefore, Nasacort Nasal Inhaler should be used with caution in patients already receiving alternate-day prednisone treatment for any disease.

PRECAUTIONS

General: In clinical studies with triamcinolone acetonide administered intranasally, the development of localized infections of the nose and pharynx with *Candida albicans* has rarely occurred. When such an infection develops it may require treatment with appropriate local therapy and discontinuance of treatment with Nasacort Nasal Inhaler.

Triamcinolone acetonide administered intranasally has been shown to be absorbed into the systemic circulation in humans. Patients with active rhinitis showed absorption similar to that found in normal volunteers. Nasacort at 440 mcg/day for 42 days did not measurably affect adrenal response to a six hour cosyntropin test. In the same study prednisone 10 mg/day significantly reduced adrenal response to ACTH over the same period (see CLINICAL TRIALS section).

Assacort Nasal Inhaler should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract or in patients with untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex.

systemic viral infections of occural refers simplex.

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, a corticosteroid should be used with caution until healing has occurred. As with other nasally inhaled corticosteroids, nasal septal perforations have been reported in rare instances.

When used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, Nasacort Nasal Inhaler should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy. Information for Patients: Patients being treated with Nasacort Nasal Inhaler should receive the

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to obtain medical advice. Patients should use Nasacort Nasal Inhaler at regular intervals since its effectiveness depends on its regular use. A decrease in symptoms may occur as soon as 12 hours after starting steroid therapy and generally can be expected to occur within a few days of initiating therapy in allergic rhintits. The patient should take the medication as directed and should not exceed the prescribed dosage. The patient should contact the physician if symptoms do not improve after three weeks, or if the condition worsens. Nasal irritation and/or burning or stinging after use of the spray occur only rarely with this product. The patient should contact the physician if they occur.

For the proper use of this unit and to attain maximum improvement, the patient should read and follow the accompanying patient instructions carefully. Because the amount dispensed per puff may not be consistent, it is important to shake the canister well. Also, the canister should be discarded after 100 actuations.

Carcinogenesis, Mutagenesis: Animal studies of triamcinolone acetonide to test its carcinogenic potential are underway.

carcinogenic potential are underway. Impairment of Fertility: Male and female rats which were administered oral triamcinolone acetonide at doses as high as 15 mcg/kg/day (110 mcg/m²/day, as calculated on a surface area basis) exhibited no evidence of impaired fertility. The maximum human dose, for companison, is 6.3 mcg/kg/day (240 mcg/m²/day). However, a few female rats which received maternally toxic doses of 8 or 15 mcg/kg/day (60 mcg/m²/day or 110 mcg/m²/day, respectively, as calculated on a

surface area basis) exhibited dystocia and prolonged delivery. Developmental toxicity, which included increases in fetal resorptions and stillbirths and decreases in pup body weight and survival, also occurred at the maternally toxic doses (2.5 - 1.5 0 mcg/kg/day or 20 - 110 mcg/kg/day or 3.8 mcg/m²/day and 7.0 mcg/m²/day).

And hor-lock of inarginary toke coses (see an a formal state).

Pregnancy: Pregnancy Category C. Like other corticoids, triamcinolone acetonide has been shown to be teratogenic in rats and rabbits. Teratogenic effects, which occurred in both species at 0.02, 0.04 and 0.08 mg/kg/day (approximately 135, 270 and 540 mcg/m²/day in the rat and 320, 640 and 1280 mcg/m²/day in the rabbit, as calculated on a surface area basis), included a low incidence of cleft palate and/or internal hydrocephaly and axial skeletal defects. Teratogenic effects, including CNS and cranial malformations, have also been observed in non-human primates at 0.5 mg/kg/day (approximately 6.7 mg/m²/day). The doses of 0.02, 0.04, 0.08, and 0.5 mg/kg/day used in these toxicology studies are approximately 12.8, 25.5, 51, and 318.7 times the minimum recommended dose of 110 mog of Nasacort per day and 32.6, 4, 12.7, and 80 times the maximum recommended dose of 440 mcg of Nasacort per day based on a patient body weight of 70 kg. Administration of aerosol by inhalation to pregnant rats and rabbits produced embryotoxic and fetotoxic effects which were comparable to those produced by administration by other routes. There are no adequate and well-controlled studies in pregnant women. Triamcinolone acetonide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Experience with oral corticoids since their introduction in pharmacologic as opposed to physiologic doses suggests that rodents are more prone to teratogenic effects from corticoids than humans. In addition, because there is a natural increase in glucocorticoid production during pregnancy, most women will require a lower exogenous steroid dose and many will not need corticoid treatment during pregnancy.

Control treatment ouring pregnancy.

Nonteratogenic Effects: Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

Nursing Mothers: It is not known whether triamcinolone acetonide is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be exercised when Nasacort Nasal Inhaler is administered to nursing women

Pediatric Use: Safety and effectiveness have not been established in children below the age of 12. Oral corticoids have been shown to cause growth suppression in children and teenagers, particularly with higher doses over extended periods. If a child or teenager on any corticoid appears to have growth suppression, the possibility that they are particularly sensitive to this effect of steroids should be considered.

ADVERSE REACTIONS: In controlled and uncontrolled studies, 1257 patients received treatment with intranasal triamcinolone acetonide. Adverse reactions are based on the 567 patients who received a product similar to the marketed Nasacort canister. These patients were treated for an average of 48 days (range 1 to 117 days). The 145 patients enrolled in uncontrolled studies received treatment from 1 to 820 days (average 332 days).

The most prevalent adverse experience was headache, being reported by approximately 18% of the patients who received Nasacort. Nasal irritation was reported by 2.8% of the patients receiving Nasacort. Other nasopharyngeal side effects were reported by fewer than 5% of the patients who received Nasacort and included: dry mucous membranes, naso-sinus congestion, throat discomfort, sneezing, and epistaxis. The complaints do not usually interfere with treatment and in the controlled and uncontrolled studies approximately 1% of patients have discontinued because of these pages adverse effects. because of these nasal adverse effects

because of these hasal adverse enects.

In the event of accidental overdose, an increased potential for these adverse experiences may be expected, but systemic adverse experiences are unlikely (see OVERDOSAGE section).

OVERDOSAGE: Acute overdosage with this dosage form is unlikely. The acute topical application of the entire 15 mg of the canister would most likely cause nasal irritation and headache. It would be unlikely to see acute systemic adverse effects if the nasal application of the 15 mg of triamcinolone acetonide was administered all at once.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription. Please see product circular for full prescribing information.

1. Data on file, Rhône-Poulenc Rorer Pharmaceuticals Inc. 2. Ziemniak JA: Pharmacokinetics of intranasal triamcinolone acetonide. J Respir Dis 1991;12 (3, Suppl):S41-S42. 3. Feiss G, Morris R, Rom D, et al: A comparative study of the effects of intranasal triamcinolone acetonide aerosol (ITAA) and prednisone on adrenocortical function. *J Allergy Clin Immunol* 1992;89:1151-1156.

4. Findlay S, Huber F, Garcia J, et al: Efficacy of once-a-day intranasal administration of triamcinolone acetonide in patients with seasonal allergic rhinitis. Ann Allergy 1992;68(3):228-232.



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Positron emission tomography (PET) image of "C-triamcinolone acetonide following intranasal administration of Nasacort

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(Continued from Page 340)

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REWARDING OPPORTUNITY to practice the full range of Family Medicine (with Obstetrical option if desired) in a long-standing community health center. BC/BE Family Practitioners needed to join existing staff composed of Family Physicians, Internists, and Pediatricians on the Waianae Coast, Academic positions also available. Full benefits package and competitive salary. If interested, call or send CV to Darlene Hoffmaster, Waianae Coast Comprehensive Health Center, 86-260 Farrington Highway, Waianae, HI 96792; (808) 696-

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ENJOY THE GREAT SOUTHWEST. Thomas-Davis Medical Centers, one of Arizona's fastest growing multispecialty groups is seeking BC/BE Internal Medicine, OB/GYN, and Hematology/Oncology Physicians. 200 physicians strong, TDMC has provided health care services in Arizona for more than 75 years. For more information regarding this practice opportunity, contact William Trainor, TDMC, 6135 N 7th St, Phoenix, AZ 85014, or call (800) 539-2529, or FAX CV to (602) 530-6255.

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CALIFORNIA. Ambulatory Care/Family Practice-CEP is a partnership of Ambulatory Care and Emergency Medicine specialists. We currently staff nine freestanding clinics in northern, central, and southern California, and have upcoming openings for physicians specializing in Family Practice. We offer shared ownership, excellent compensation, health, and disability insurance, retirement program, and many other benefits. For more information, send CV or call John Gravette, CEP, 2101 Webster St, Ste 1050, Oakland, CA 94612; (800) 842-2619.

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(Continued from Page 341)

PHYSICIANS WANTED



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AT NO COST TO PHYSICIAN

(Continued from Page 342)

PHYSICIANS WANTED

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Kathleen Strawbridge **Medical Staff Coordinator** Sunnyvale Medical Clinic 301 Old San Francisco Rd Sunnyvale, CA 94086 (408) 730-4309



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(Continued on Page 344)

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Excellent opportunity for PC physician interested in a college health career. SDSU Student Health Services, a nationally recognized, AAAHC accredited clinic located in "America's Finest City" is seeking CA licensed, BC physicians for permanent full-time ten-month positions. Experience with adolescents/young adults preferred. Clinic also involved in research projects and coordinates the UCSD/SDSU Preventive Medicine Residency. Generous benefits package. Send résumé to: Kimberly Johnson, Student Health Services, San Diego State University, 5500 Campanile Dr, San Diego, CA 92182-4701.

SDSU is committed to a diverse workforce and affirmative action and is an EEO employer. SDSU does not discriminate against physically challenged persons.

The Prescott VA Medical Center is seeking BC/BE Internal Medicine physicians, one with an interest in Infectious Disease, as full-time staff physicians to provide primary care. Prescott, the "milehigh" Old West city is conveniently located 98 miles north of Phoenix, the state capital. At an altitude of 5,300 feet, the city is nestled in the mountainous, ponderosa pine area of north central Arizona. Lots of sun in a dry four-season climate, fresh air. and recreation abound. Money Magazine rates Prescott. Arizona as the number one city to live in. Malpractice is covered. Interested and qualified candidates should send CV to:

Bruce Manziello, MD, FACP Chief of Staff VA Medical Center Attn: (11) Prescott, AZ 86313 or call (602) 776-6009



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PACIFIC NORTHWEST: WASHINGTON, OREGON, IDAHO. BC/BE physicians needed, Family Practice, Internal Medicine, OB/GYN, Pediatrics, Emergency Medicine Director. Call Eva Page, Page & Associates, Physician Recruiting, (800) 833-3449 or send CV to 1420 NW Gilman Blvd, Ste 2133, Issaquah, WA 98027.



(Continued from Page 344)

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(Continued on Page 346)

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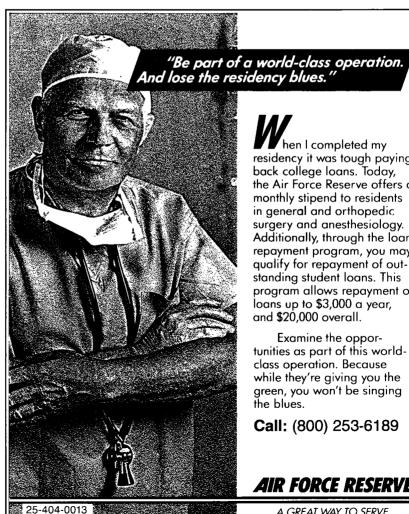
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(Continued from Page 345)

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NEURONTIN®

(Gabapentin Capsules)

Before prescribing, please see full prescribing information. A Brief Summary follows

INDICATIONS AND USAGE

tin) is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with enileasy

CONTRAINDICATIONS

Neurontin® is contraindicated in nations who have demonstrated hypersensitivity to the data or its incredients

WARNINGS

WARKINGS
Withdrawal Precipitated Seizure, Status Epilepticus
Anteplainic drugs should not be dumptly discontinued because of the possibility of increasing seizure frequency.
In the placebocontrolled studies, the incidence of status epilepticus in potients receiving Neurontin® was 0.6% (5 of 543) wesus 0.5% in patients receiving placebo (2 of 378).
Among the 2073 patients reseted with Neurontin® across oil studies (controlled and uncontrolled) 31 (1.5%) had status epilepticus. Of these, 14 patients had no prior history of status epileptias either before treatment or while on other medications. Because adequate historiad data or not orwalder, it is impossible to say whether or not Neurontin''s associated with a higher or lower rate of status epileptias than would be expected to occur in a similar population not treated with Neurontin''s

Tumorigenic Potential

In standard previous in vitro lifetime corrinogenicity studies, on unexpectedly high incidence of pararetric acrian adenocarainomas was identified in male, but not fernale, mits. (See PRECULTIONS: Carainogenesis, Mutagenesis, Impairment of Fentilly.) The dinical significance of this finding is unknown. Clinical experience during gadapentin's premarketing

development provides no direct means to assess is potential for inducing tumors in humans.

In direct studies comprising 2085 parlierty-ass of exposure, new humans were reported in 10 parlients (2 breast, 3 brain, 2 lung, 1 advend, 1 mort-hodglion's lymphomore, 1 endometrial corrisonom in situ), and precediting tumors worsered in 11 parlients (9 brain, 1 breast, 1 prostate) during or up to 2 years following discontinuction of Neurontine.

Without knowledge of the background incidence and recurrence in a similar population negli treated with Neurontine. It is impossable to know whether the incidence seen in this cohort is or is not affected by treatment.

Sudden and Unexplained Deaths

arketing development of Neurontin®, 8 sudden and unexplained deaths were recorded among a cohort of 2203 patients treated (2103 patient-years of exposure)

of exposure).

Some of these could represent seizure-related deaths in which the seizure was not observed, e.g., at night. This represents on incidence of 0.0038 deaths per patient-year.

Although this rate exceeds that experted in a healthy population matched for age and sex, it is within the range of estimates for the incidence of sudden unexplained deaths in patients with epileps not receiving Neuronin* (ranging from 0.0005 for the general population of epileptics, to 0.003 for a clinical third population similar to that in the Neuronin* program, to 0.005 for patients with reflactory epileps). (consequently, whether these figures are reassuring or moise further concern depends on comparability of the populations reported upon to the Neurontin® cohort and the accuracy of the estimates provided.

Information for Patients

**International for a reservation of the Neuroninal only as prescribed. Patients should be instructed to take Neuroninal only as prescribed. Patients should be advised that Neuroninal only as prescribed. Patients should be advised that Neuroninal only as prescribed on the symptoms and signs of CNS degression. Accordingly, they should be advised neither to drive a car now to operate other complex moditionery until they have gained sufficient experience on Neuroninal to gauge whether or not it affects their mental and/or motor.

oratory Tests Tricked hids date on indicate that routine monitoring of clinical blooratory parameters is necessary for the safe use of Neurontin®. The value of monitoring Neurontin® blood concentrations has not been established. Neurontin® may be used in combination with other antiepileptic drugs without concern for attention of the blood concentrations of gabaperatin or of other antiepileptic drugs.

Drug Interactions

Drug Interactions
Catopenin is not appreciately metabolized not does it interfere with the metabolism of commonly coadministered antispileptic drugs.
The drug interaction data described in this section were obtained from studies involving healthly adults and patients with epilepsy.
Phenytrial. In a single and multiple does study of Neuronine* (400 mg 1.1.0.) in epilepty patients (N = 8) monitarized on phenytrian monotherapy for at least 2 months, appropriate. In a single and multiple does study of Neuronine* (400 mg 1.1.0.); in epilepty patients (N = 8) monitarized on phenytrian monotherapy for at least 2 months, appropriate, Study-stude though plasma conformacepine and conformacepine (0, 11 epoxides concentrations were ort different on the study plasma conformacepine and conformacepine orbinatrations.

Valuation Adult.** The mean steady-stude though searn valpric and concentrations prior to and during concomitant galaxyering administration (400 mg 1.1.0.; N = 17) were not different and neither were galaxyering hormocokinetic parameters of the valoric and.

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administered alone or together

Phesochamber III. Stimples of stocky-strip phomococknetic parameters for phenobarbital or gobopentin (300 mg T.I.D.; N = 12) are identical whether the drugs are administed done or together.

Cimetillian. In the presence of cimetidine at 300 mg 0.I.D. (N = 12) the mean apparent and clearance of gobopentin fell by 14% and creatinine desarance fell by 10%. This cimetidine appearant to other the presence of cimetidine and continue, an endogenous marker of read function. This small decrease in excertion of gobopentin by cimetidine is not expected to be of clinical importance. The effect of gobopentin or cimetidine was not evaluated.

Oral Contraceptive. Based on AIC and half-life, multiple-dose pharmocolimeir parties of norethinature and ethinyl estradoid lookwing administration of bables containing 2.5 mg of norethinature was 13% higher when commissioned with appearing this interaction is not expected to be of critical importance.

Austracid (Manulax **). Motion: reduced the biocondibility of gobopentin (N = 16) by doort 20%. This decrease in biocondibility was about 5% when gobopentin was administrated 2 hours often Madaics. It is recommended that gobopentin be tolerent at least 2 hours following Madaic administration.

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Pregamery
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always predictive of human response, this drug stould be used during pregnancy only if the potential benefit justifies the potential risk to the tetus.

Use in Neurosian Monthers
It is not known if gatoppentin is excreted in human milk and the effect on the nursing infant is unknown. However, because many drugs are excreted in human milk, Neurontin® should be used in women who are nursing only if the benefits dearly outweigh the risks.

Pediatrinic Use.

Safety and effectiveness in dilation below the age of 12 years have not been established.

Geriatric Use

Gentaritic Use

No systematic studies in geniatric patients have been conducted. Adverse clinical events reported among 59 Neurontin® exposed potients over age 65 did not differ in kind from those reported for younger individuals. The small number of older individuals evaluated, however, limits the strength of any conclusions reached about the influence, if any, of age on the kind and incidence of obverse events or indomotry abnormality associated with the use of Neurontin's Reaccise Neurontin's individuals in eliminated principle by the real exception, the does of Neurontin's Household be adjusted on roted in DOSAGE AND ADMINISTRATION (Table 2) for elderly potients with compromised renal function. Creatinine decorates is difficult to measure in outpatients and serum creatinine may be reduced in the elderly because of decreased muscle mass.

Creatinine decorates (C_c) can be reasonably well estimated using the equation of Cockcroft and Soult:

for females

C_c = (140—age) (wr) / (1/2) (S_c) |

for males

C_c = (140—age) (wr) / (1/2) (S_c) |

APPLYESSE REACTIONS

ADVERSE REACTIONS

ADVERSE REACTIONS

The most commonly observed otherse events associated with the use of Neurontin® in combination with other antiepileptic drugs, not seen at an equivalent frequency among placebot-treated patients, were somolence, dizziness, attació, fotique, and instagraus.

Apparaimentely 7% of the 2073 individuals who reserved Neurontin® in premarketing dinical brids discontinued treatment because of an otherse event. The otherse events most commonly associated with windifferant were somolence (1.2%), attació (0.8%), fatigue (0.6%), naussea and/or vormiting (0.6%), and dizziness (0.6%).

Incidence in Controlled Clinical Tritals

Commonly associated with initiative were symmetric (1.7.4), autous (2.0.4), ranges (2.0.4), masses used to common in the Neuronitin® from the common in the Neuronitin® more common in the Neuronitin® group. In these studies, either Neuronitin® more common in the Neuronitin® group, in these studies, either Neuronitin® or placebo was added to the patient's current antiepilepric drug therapy. Adverse events

numerically most common in the Resonant's group, in insest source, either resonant or purchase when source and interestly.

The prescribes should be everal that these figures, obtained when Neuronina* was added to concurrent antispilleptic drug therapy, connot be used to predict the frequency of otherse events in the course of usual medical practice where patient characteristics and other factors may differ from those prevailing during directly studies. Similarly, the cited frequencies connot be directly compared with figures obtained from other clinical investigations involving different treatments, uses, or investigations. An inspection of these

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frequencies, however, does provide the prescribing physician with one basis to estimate the relative contribution of drug and nondrup factors to the adverse event incidences in the

TABLE 1. Treatment-Emergent Adverse Event Incidence in Controlled Add-On Trials (Events in at least 1% of Neurontin patients and numerically more frequent than in the

Body System/ Adverse Event	Neurontin®o N=543 (%)	Plocebo° N=378 (%)	Body System/ Adverse Event	Neurontin® N=543 (%)	Plocebo° N=378 (%)
Body As A Whole			Nervous System (cont'd)		
Fatigue	11.0	5.0	Tremor	6.8	3.2
Weight Increase	2.9	1.6	Nervousness	2.4	1.9
Bock Pain	1.8	0.5	Dysarthria	2.4	0.5
Peripheral Edema	1.7	0.5	Amnesio	2.2	0.0
Cardiovascular			Depression	1.8	1.1
Vasadilatation	1.1	0.3	Thinking Abnormal	1.7	1.3
Digestive System			Twitching	1.3	0.5
Dyspepsia	2.2	0.5	Coordination Abnormal	1.1	0.3
Mouth or Throat Dry	1.7	0.5	Respiratory System		
Constinution	1.5	0.8	Rhinitis	4.3	3.7
Dental Abnormalities	1.5	0.3	Pharyngitis	2.8	1.6
Increased Appetite	1.1	0.8	Coughing	1.8	1.3
Hematologic and Lymphatic Sys	stems		Skin and Appendages		
Leukopenia	1.1	0.5	Abrasion	1.3	0.0
Musculoskeletal System			Pruritus	1.3	0.5
Myalgia	2.0	1.9	Urogenital System		
Frocture	1.1	0.8	Impotence	1.5	1.1
Nervous System			Special Senses		
Somnolence	19.3	8.7	Diplopia	5.9	1.9
Dizziness	17.1	6.9	Amblyopia ^b	4.2	1.1
Ataxia	12.5	5.6	Laboratory Deviations		
Nystagmus	8.3	4.0	WBC Decreased	1.1	0.5

^{*} Plus background antiepileptic drug therapy * Amblyopia was often described as blurred vision

There events in more than 1% of patients but equally or more frequent in the placeba group included; headache, viral infection, fever, nousea and/or vaniting, doborminal pain, domined, convolutions, controlors, controlors,

In continuous and the property of the property of the previous totals are reported events are inducted to the previous totals and the previous totals are reported to exhibit a positive descriptions relationship.

The overall incidence of otherse events and the types of otherse events seen were similar among men and women treated with Neuronini*. The incidence of otherse events increased signify with ancessing age in patients treated with either Neuronini* or picacio. Because only 3% of patients (28/9/21) in picacio-controlled studies were identified as non-white (Bock or other), there are invalidated and the property of the Controlled Studies were identified as non-white (Bock or other), there are invalidated and and clinical Trials

Neuronini* has been orbinished to 20/4 individuos during all clinical trials. Only some of which were placebo-controlled. During these trials, all otherse events were recorded by the direct investigators using terminology of their own chossing. In provide a meaningful estimate of the proportion of individuos having adverse events, smilar types of events were appoind into a smaller number of standardized artegories using monified (OS/IAI) discharge terminology. These orbinations are in the standardized events are included except these adversely in the province of the proportion of individuos having adverse events, smilar types of events were appoind into the proportion of the 20/4 individuos because the receiving the province of the properties of the proportion of an electron account of the properties of the proportion of t

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Body As A Whole: frequent: osherio, motiose, toce etemo; introquent: ostery, generatized ecenius, wayin accross, cum, and control introductic, brogner effect.

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busitis, controcture.

Nerviews Systems: Frequent: vertigo, hypertinesia, paresthesia, decreased or dosent reflexes, increased reflexes, arcively, hostiliny, infrequent: CIS tumors, syncope, determing domand, opinicos, hypertinesia, introcroad hemorandia, paresthesia, paresthesia, parest, dystamia, hemplegai, flood paroliss, stupor, cerebellar dystunction, positive Bolinistis sign, decreased position seess, subdural hemorano, quality, halluciration, decrease or loss of libido, agointoin, paramosi, beges sonalizationia, exploria, feeling high, dopertup secretion, suicidal, psychosis; flore: characteristics, load impolarme, propriettiesis, hypokinesia, maria, neurosis, hysteini, artiscoal reaction, suicide gestue.

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Dermantological: Infraquent: dopocia, ezerna, dry skin, increased sweating, unitaria, hisulfam, seborthea, cyst, herpes simplex; Rare: herpes zoster, skin discolor, skin popules, photoserative exotion; leg uter, scap seborthea, porasis, desquantion, moreoning, skin motions, bundresspantial Systems: Infraquent: hermation, dysam; control requestor, cystis, unitary retentions, unitary reconstructs, regular thermations, dysam; control requestor, cystis, unitary retentions, unitary reconstructs, regular thermation uppears, varieties opini, best control, graving, unitarian uppears, varieties uppears, varieties print, services, produce the control production production and vision; Infraquent: colorout, conjunctivitis, eyes dry, eye poin, visual field defect, photophobia, bilateral or unitariated pricis; eye hemorrhoge, hordeolum, herming loss, exarche, trainitis, inner en infection, offits, laste lass, unusual tasts, eye hirtiding, our foliares, fore: eye etitoria, globornal control, composition depenantion, depenantive eye charges, bilanderss, retiral depenantion, missis, choiserenties, straiserus, eustachian tate dysturction, labyrinthis, othis externa, odd smel.

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DRUG ABUSE AND DEPENDENCE
The abuse and dependence potential of Neurontin® has not been evaluated in human studies.

OVERDOSAGE

A lethal dose of autoacentin was not identified in mice and rats receiving single and doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxico, labored

A lettria use or gausquarian man an accument in the second of the second tients recovered with supportive core

patients recovered with supporting care. Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state nts with significant renal impairm DOSAGE AND ADMINISTRATION

DOSAGE AND ADMINISTRATION

Neuronin® is excommended to address therapy in potients over 12 years of oge. Evidence bearing on its safety and effectiveness in children is not available.

Neuronin® is great only with or without frood.

The effecte dose of Neuronin® is 900 to 1800 mg/day and given in divided doses (three times a day) using 300 or 400-mg capasies. Timotion to an effective dose can take pote rapidly, over a few days, giving 300 mg and Dey 1, 300 mg in Vec a day on Dey 2, and 300 mg three times a day on Dey 3. To minimize potential side effects, especially sommalerus, discribes, fortigue, and attaco, the lists dose on Dey 1 may be administrated at bedfilme. If necessary, the dose may be increased using 300-or 400-mg capasies three times a day to 1800 mg/day, bosques up to 2400 mg/day have been well between thing the interest because the in ELLD, schedule should not exceed 12 hours. It is not necessary to manifer potagonarin piesma concentrations to opinize Neuronin® and other commantly used antiepiepic drugs, the addition of Neuronin® does not after the plasma levels of these drugs approachly. If Neuronin® and their commantly used antiepiepic drugs, the addition of Neuronin® added to the theory, this should be done groupally over a minimum of 1 week.

Desage adjustment in puteriors with comproneed read function or underpoing hemodayles is recommended as follows:

TABLE 2. Neurontin® Dosgoe Based on Renal Function

Renal Function Creatinine Clearance (mL/min)	Total Daily Dose (mg/day)	Dose Regimen (mg)
>60	1200	400 T.I.D.
30-60	600	300 B.I.D.
15-30	300	300 Q.D.
<15	150	300 Q.O.D.°
Hemodialysis	-	200-300 ^b

PARKE-DAVIS

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Every other day
Loading dose of 300 to 400 mg in patients who have never received Neurontin®, then 200 to 300 mg Neurontin® following each 4 hours of hemodialysis

NEURONTINgabapentin capsules 100 mg, 300 mg, 400 mg

ADDED SEIZURE CONTROL ...



...THAT'S EASY TO HANDLE

- In clinical trials with difficult to treat patients (>12 years),* NEURONTIN adjunctive therapy improved control of partial seizures, including secondarily generalized tonicclonic seizures¹
- Simple, predictable pharmacokinetics¹
- No pharmacokinetic interactions with carbamazepine, phenobarbital, phenytoin, or valproic acid¹
- Well-tolerated adjunctive therapy¹
- Rapid 3-day titration to an effective dose

In clinical trials, the most common adverse events associated with NEURONTIN use were CNS related, primarily mild to moderate in intensity, and included somnolence (19.3%), dizziness (17.1%), ataxia (12.5%), fatigue (11%), and nystagmus (8.3%). NEURONTIN is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

* These patients had inadequate seizure control with their anticonvulsants (eg, carbamazepine, phenobarbital, phenytoin, valproic acid); could not tolerate their agents; or could not tolerate high-enough doses for seizure control. Please see brief summary of full prescribing information on the next page.

REFERENCE

1. Data on file, Parke-Davis.

